

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

JOHN D. PUSKAS, M.D.

Filed: January 16, 2002

Serial No. 10/051,752

For: "APPARATUS FOR INDIRECTLY  
STIMULATING THE VAGUS NERVE  
WITH AN ELECTRICAL FIELD"

## SUBSTITUTE PRELIMINARY REMARKS

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Prior to examining the application identified above, please consider the following remarks:

## REMARKS

*Summary of the Claims and Support Therefor*

The newly added claims all relate to apparatus for stimulating a vagus nerve by means of an electric field generated by a pair of electrodes. Claims 1-12 relate to an apparatus in which a pair of electrodes are located in spaced-apart relation in the esophagus. Specifically, Claim 1 recites an apparatus comprising a pair of electrodes positioned within the esophagus of the patient in spaced apart relation, with a means operatively associated with the

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Theodore M. Green - Reg. No. 41,801

electrodes for actuating at least one of the electrodes to create an electrical field effective to stimulate the vagus nerve. Claim 2 adds the limitation that the electrodes are spaced apart by about 1 cm. Support for Claims 1 and 2 is found in the specification, *e.g.*, at page 8, lines 5–19, which discloses electrical stimulation of a vagus nerve (“stimulation of the right or left vagus”) by inserting a pair of electrodes (“other suitable stimulators include a pair of pacing wires or electrodes placed about 1 cm apart”) into the esophagus of the patient (“stimulation ... in the internal jugular vein, esophagus, or trachea”) (emphasis added). In addition, the specification at p. 10, lines 23–26, provides that “Vagal stimulation was performed with a nerve stimulator (Grass Instrument Co, Quincy, MA) in the monopolar mode at a frequency of 40 Hz, an impulse duration of 0.4 msec, and an amplitude of 2–6 volts.”

Claim 3 is dependent from Claim 1 and adds the limitation that both electrodes are actuated. Claim 4 recites that the electrodes may be actuated in either unipolar or bipolar mode. Support is found in the specification, *e.g.*, at page 8, lines 5–19 (“Other suitable locations for vagus nerve stimulation include ... unipolar or bipolar electrical stimulation”).

Claim 5 is dependent from Claim 1 and recites that the vagus nerve is stimulated for a period of between about five and about ninety seconds. Claim 6 is dependent from Claim 5 and limits the period of stimulation to 5 to 15 seconds. Support is found in the specification, *e.g.*, at page 8, lines 5–19 (“A single continuous impulse is applied of between about 5 seconds to about 90 seconds, preferably between about 5 seconds and about 15 seconds”).

Claim 7 recites that the means for actuating the electrode to create an electrical field applies an impulse at a frequency of between about one Hertz and about five hundred Hertz. Claim 8 limits the frequency to 20–80 Hz, and Claim 9 recites a frequency of about 40 Hz.

Support is found in the specification, *e.g.*, at page 8, lines 5–19 (“Impulse parameters can readily be varied, *e.g.*, a frequency range of between about 1Hz and about 500Hz, preferably between about 20 Hz to about 80Hz, more preferably about 40 Hz”).

Claim 10 recites that the duration of the pulse is 0.4 msec. Support is found in the specification at p. 10, lines 23–26 (“Vagal stimulation was performed with a nerve stimulator ... in the monopolar mode at a frequency of 40 Hz, an impulse duration of 0.4 msec, and an amplitude of 2–6 volts.”)

Claim 11 recites a voltage of 1–40 volts. Support is found in the specification, *e.g.*, at page 8, lines 5–19 (“Impulse parameters can readily be varied, *e.g.*, a frequency range of between about 1Hz and about 500Hz, preferably between about 20 Hz to about 80Hz, more preferably about 40 Hz, with an amplitude between about 1 to about 40 volts.”) Claim 12 recites a voltage of 2–6 volts. Support for Claim 13 is found in the specification at p. 10, lines 23–26 (“Vagal stimulation was performed with a nerve stimulator ... in the monopolar mode at a frequency of 40 Hz, an impulse duration of 0.4 msec, and an amplitude of 2–6 volts.”)

Claim 13–24 is similar to Claims 1–12 except that the pair of electrodes is located in the trachea. Support for this limitation is found, *e.g.*, at p. 8, lines 5–20 (“Other suitable locations for vagus nerve stimulation include ... stimulation with a percutaneous catheter or electrode probe in the internal jugular vein, esophagus, or trachea”).

Claims 25–36 are similar to Claims 1–12, except the electrodes are positioned within a jugular vein. Support for this limitation is found, *e.g.*, at p. 8, lines 5–20 (“Other suitable

locations for vagus nerve stimulation include ... stimulation with a percutaneous catheter or electrode probe in the internal jugular vein")

Claims 37–48 are similar to Claims 1–12, except the electrodes are positioned on the patient's neck. Support for this limitation is found, *e.g.*, at p. 8, lines 5–20 ("Electrical stimulation is carried out on the right vagus nerve, preferably at a site on the neck.")

Claims 49–60 are similar to Claims 1–12, except that one electrode is positioned in the esophagus, and the second electrode is positioned in the trachea. Support for this limitation is found, *e.g.*, at p. 8, lines 5–20 ("Other suitable locations for vagus nerve stimulation include ... stimulation with a percutaneous catheter or electrode probe in the internal jugular vein, esophagus, or trachea, or combination of these.").

Claims 61–72 are similar to Claims 1–12, except that one electrode is positioned in the esophagus, and the second electrode is positioned in a jugular vein. Support for this limitation is found, *e.g.*, at p. 8, lines 5–20 ("Other suitable locations for vagus nerve stimulation include ... stimulation with a percutaneous catheter or electrode probe in the internal jugular vein, esophagus, or trachea, or combination of these.").

Claims 73–84 are similar to Claims 1–12, except that one electrode is positioned in the esophagus, and the second electrode is positioned on the neck. Support for this limitation is found, *e.g.*, at p. 8, lines 5–20 ("Electrical stimulation is carried out on the right vagus nerve, preferably at a site on the neck. Other suitable locations for vagus nerve stimulation include ... stimulation with a percutaneous catheter or electrode probe in the internal jugular vein, esophagus, or trachea, or combination of these.").

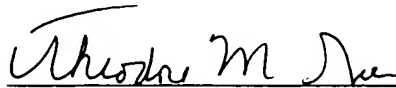
Claims 85–96 are similar to Claims 1–12, except that one electrode is positioned in the trachea, and the second electrode is positioned in the jugular vein. Support for this limitation is found, *e.g.*, at p. 8, lines 5–20 (“Other suitable locations for vagus nerve stimulation include ... stimulation with a percutaneous catheter or electrode probe in the internal jugular vein, esophagus, or trachea, or combination of these.”).

Claims 97–108 are similar to Claims 1–12, except that one electrode is positioned in the trachea, and the second electrode is positioned on the neck. Support for this limitation is found, *e.g.*, at p. 8, lines 5–20 (“Electrical stimulation is carried out on the right vagus nerve, preferably at a site on the neck. Other suitable locations for vagus nerve stimulation include ... stimulation with a percutaneous catheter or electrode probe in the internal jugular vein, esophagus, or trachea, or combination of these.”).

Claims 109–120 are similar to Claims 1–12, except that one electrode is positioned in the jugular vein, and the second electrode is positioned on the neck. Support for this limitation is found, *e.g.*, at p. 8, lines 5–20 (“Electrical stimulation is carried out on the right vagus nerve, preferably at a site on the neck. Other suitable locations for vagus nerve stimulation include ... stimulation with a percutaneous catheter or electrode probe in the internal jugular vein, esophagus, or trachea, or combination of these.”).

Examination of the application at an early date is requested in view of the foregoing remarks.

Respectfully submitted:

A handwritten signature in cursive script, appearing to read "Theodore M. Green", is written over a horizontal line.

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